



Memorandum

Date: February 14, 2006
To: Pediatric Subcommittee of the Oncologic Drugs Advisory Committee Members, Consultants, and Guests
From: Karen D. Weiss, M.D.
Deputy Director, Office of Oncology Drug Products, CDER, FDA
Subject: FDA Background Package for March 14, 2006 Meeting

This memo outlines the topics for discussion at the March 14, 2006 meeting of the Pediatric Subcommittee to ODAC. This session is divided into three parts.

The first half of the morning will be devoted to discussions of proposals for the study of two off-patent drugs used in pediatric oncology, daunomycin and methotrexate. Both are on the priority list per the Best Pharmaceuticals for Children Act (BPCA). For daunomycin, the main focus is the relationship between daunomycin pharmacokinetics and patient demographic factors, particularly body size and body composition. For methotrexate, the major issues are efficacy and safety, and in particular neurocognitive adverse outcomes, of high dose methotrexate, and to how best to predict who might be at risk of developing these adverse outcomes. We seek your input as we develop Written Requests for these drugs.

The next topic is Exjade® (deferasirox), the first oral iron chelator. It is manufactured by Novartis and was approved under the accelerated approval mechanism on November 2, 2005 for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and over. We will summarize the data supporting the safety and efficacy of Exjade® and seek your input on study designs to meet the phase 4 commitments.

The afternoon session is devoted to a general discussion of drug shortages. The session will begin with two presentations. The first, from a representative of regulated industry, will provide an industry perspective on shortages, and the second, from a member of CDER's Drug Shortage Team, will highlight FDA's role in potential or actual drug shortages. Following the presentations, we will seek your input for ways to minimize and respond to drug shortages in pediatric oncology.

As always, thank you in advance for your willingness to devote your time to the pediatric subcommittee, and I look forward to your input on March 14.